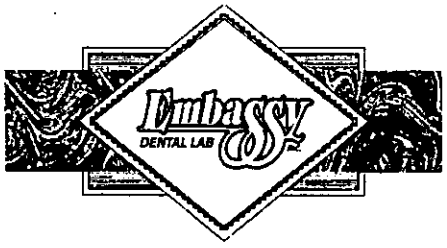
K111069

JUL 2 2 2011



510(k) Summary

Date:	**8 April 2011**
Sponsor:	**Embassy Dental Laboratory, Inc.** 11825 North Route 40, #103 Dunlap, IL 61525 Phone: 309-243-1714 Fax: 309-243-1945
Contact Person:	Rodney Willey, DDS, President
Proposed Trade Name:	Acrylic Herbst Appliance
Device Classification	Class II
Classification Name:	Device, Anti-Snoring
Regulation and Name:	872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Product Code:	LRK
Device Description:	The Acrylic Herbst Appliance is comprised of custom-fabricated acrylic splints (methylmethacrylate) which are connected bilaterally via a telescoping Herbst mechanism (stainless steel).
Intended Use:	The Acrylic Herbst Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.
Predicate Devices:	Allesee Orthodontic Appliances, Inc. (K070327) Specialty Appliances Works, Inc. (K083209) Dynaflex Inc. (K103076)
Technological Characteristics:	The Acrylic Herbst Appliance possesses the same technological characteristics as one or more of the predicate devices. These include: • Anatomic location (intraoral), • Basic design (mandibular repositioning using upper and lower acrylic trays with bilateral Herbst mechanisms), • Materials (methylmethacrylate and stainless steel) and • Manufacture (appliance is fabricated by prescription to the specific requirements of a single patient) The fundamental scientific technology of the Acrylic Herbst Appliance is the same as previously cleared devices.

Conclusion:

In comparison to the predicate devices, the Acrylic Herbst Appliance has

- the same intended use (as described above),
- the same technological characteristics (as described above)

and so does not raise new questions of safety and effectiveness. Therefore the Acrylic Herbst Appliance can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Embassy Dental Laboratory
C/O Karen E. Warden, PhD
President
Backroads Consulting, Incorporated
8202 Sherman Road
Chesterland, Ohio 44026

JUL 2 2 2011

Re: K111009
Trade/Device Name: Acrylic Herbst Appliance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: June 22, 2011
Received: June 27, 2011

Dear Dr. Werden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Richard C. Chapman for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K111009

Device Name: **Acrylic Herbst Appliance**

Indications for Use:

The Acrylic Herbst Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 7/22/11

(Division Sign-Off)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

510(k) Number: K111009